

The claims are directed to methods for making cell-matrix constructs. A fibrous matrix is first implanted into a site in a human or an animal, where tissue ingrowth occurs. Then the matrix is removed and implanted into a second site in a human or animal. As explained in the specification at page 12, lines 18-21, the recipient or an animal is used as a bioreactor to form a fibrous tissue-polymeric construct which can be seeded with other cells and implanted. The implant is ultimately used at a site which is different from that where the initial culturing is performed.

Rejection Under 35 U.S.C. § 103

Claims 6-12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,514,791 to Sparks ("Sparks"), in combination with U.S. Patent No. 4,801,299 to Brendel, et al. ("Brendel"), U.S. Patent No. 4,902,289 to Yannas ("Yannas"), and U.S. Patent No. 5,772,695 to Orton ("Orton"). Applicants respectfully traverse this rejection.

Sparks

Sparks is directed to growing tissue on a solid stainless steel tube. (see col. 3, lines 29-34) The tube may be prefilled with a patient's own blood. Sparks teaches that "the blood will immediately clot within the [tube] so that it will not escape through perforations." (col. 3, lines 74-75) Once in the patient's body, the blood is absorbed and replaced with the invading connective tissue. Sparks does not teach or suggest implanting a matrix into one site, removing the matrix after tissue ingrowth has occurred, and then implanting the matrix into a second site where the cell construct is needed.

Brendel

Brendel is directed to cell-free extracellular matrices. Brendel teaches that the "extracellular membranes, nucleic acids, lipids, and cytoplasmic components" must be removed before the matrix is implanted in a patient. (see col. 2, lines 28-31). Brendel takes natural body tissue from animals and humans and the washes the tissue with detergents to remove cellular components from the tissue to obtain sterilized tissue which can then be implanted into a human. (see col. 4, lines 15-30) All or the tissue is obtained upon autopsy or sacrifice. Brendel does not teach or suggest implanting a matrix into a site, allowing for tissue ingrowth to occur, removing the matrix, and implanting it into a second site.

Yannas

Yannas is directed to a multilayer blood vessel prosthesis. The prosthesis is thromboresistent. Yannas states, "Of course the material of the blood vessel is compatible with blood and does not cause platelet aggregation or activation of critical steps of the intrinsic and extrinsic coagulation cascades." (col. 2, lines 2-6) Yannas does not teach or suggest implanting a matrix into a site, allowing for tissue ingrowth to occur, removing the matrix, and implanting it into a second site.

Orton

Orton is directed to modified grafts. Orton teaches treating xenogeneic or allogeneic tissue with a growth factor and native cells before implantation in a patient. Orton does not teach or suggest implanting a matrix into a site, allowing for tissue ingrowth to occur, removing the matrix, and implanting it into a second site.

The Combined References

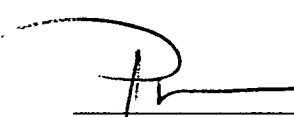
Nothing in these references teaches or suggests combining them. Sparks teaches that blood clot formation is helpful, Yannas stress the importance of being thromboresistant. Therefore, the references themselves teach away from their combination. Further, Sparks is directed to implanting a solid stainless steel tube into a patient's body and allowing the patient's own cells to grow into the tube, while Brendel and Orton are directed to allografts and xenografts. The Examiner has not cited anything in these references that would suggest their combination.

However, even if one of skill in the art combined Sparks with Brendel, Yannas, and Orton, Applicants' methods would not be obvious. Even when read together, these patents do not teach Applicants' method of implanting a matrix into a site, allowing for tissue ingrowth to occur, removing the matrix, and implanting it into a second site. Thus the claimed methods are not obvious.

U.S.S.N. 09/185,360
Filed: November 3, 1998
RESPONSE TO OFFICE ACTION

Allowance of claims 6-12 is respectfully solicited.

Respectfully submitted,



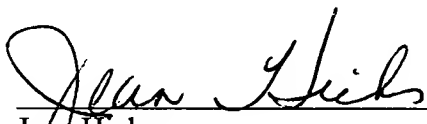
Patrea L. Pabst
Reg. No. 31,284

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ARNALL, GOLDEN & GREGORY, LLP
2800 One Atlantic Center
1201 West Peachtree Street
Atlanta, Georgia 30309-3450
(404) 873-8794
(404) 873-8795 (fax)

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I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.



Jean Hicks

Date: November 1, 2000